NovaSure®
Instructions for Use and Controller Operator's Manual

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CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN TRAINED IN THE USE OF THE DEVICE.

Read all instructions, cautions and warnings prior to use. Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury.

NOTE: The manual that accompanied the disposable device may contain a more recent revision of the NovaSure system instructions than the manual provided with the controller.

The NovaSure disposable device is not to be used with other controllers and/or RF generators, and the NovaSure RF controller is not to be used with other disposable devices.

The NovaSure disposable device does not contain latex.

Physician Checklist

The physician must:

- have sufficient experience in performing procedures within the uterine cavity, such as IUD insertion or dilation and curettage (D&C) and with adequate training, knowledge and familiarity using the NovaSure system;
- review and be familiar with the instructions and complete either NovaSure training or be trained by a qualified physician;
- be aware of the appropriate sequence of actions detailed in the Instructions for Use and Troubleshooting sections of this manual to abort, resolve and/or continue the treatment in the event the system detects a loss of CO_2 during the cavity integrity assessment (CIA), which indicates a possible uterine perforation.

Adjunct personnel must be familiar with these instructions and other training materials prior to using the NovaSure system.

System Description

The NovaSure impedance controlled endometrial ablation system consists of the NovaSure disposable device with connecting cord, NovaSure RF controller (controller), NovaSure CO_2 canister, desiccant, foot switch and power cord, which are designed to be used together as a system.

NovaSure Disposable Device with Connecting Cord, Including Suction Line Desiccant

NovaSure Disposable Device Description

The NovaSure disposable device consists of a single-patient use, conformable bipolar electrode array mounted on an expandable frame that can create a confluent lesion on the entire interior surface area of the uterine cavity. The disposable device is inserted transcervically into the uterine cavity, and the sheath is retracted to allow the bipolar electrode array to be deployed and conform to the uterine cavity.

The bipolar electrode array is formed from a metalized, porous fabric through which steam and moisture are continuously suctioned from the desiccated tissue. The disposable device works in conjunction with a dedicated NovaSure RF controller to perform customized, global endometrial ablation in an average of approximately 90 seconds without the need for concomitant hysteroscopic visualization or endometrial pretreatment. The specific configuration of the bipolar electrode array and the predetermined power of the controller create a controlled depth of ablation in uteri sounding less than or equal to 10 cm and having a minimum cornu-to-cornu distance of 2.5 cm.

During the ablation process, the flow of radio frequency (RF) energy vaporizes and/or coagulates the endometrium regardless of its thickness and desiccates and coagulates the underlying, superficial myometrium.

The controller automatically calculates the optimal power level (W) required for the treatment of the uterine cavity, based on uterine size. As tissue destruction reaches an optimal depth, increasing tissue impedance causes the controller to automatically terminate power delivery, thereby providing a self-regulating process. Blood, saline and other liquid present in the uterine cavity at the time of the procedure, as well as vapor liberated from the desiccated tissue, are evacuated by continuous, automatic suctioning.

The disposable device is connected to the controller via a cord containing the RF cable, suction tubing used for pressure monitoring during the cavity integrity assessment cycle and for suction during the ablation cycle, and vacuum feedback tubing used for carbon dioxide delivery during the cavity integrity assessment cycle and vacuum monitoring during the ablation cycle. The disposable device has been sterillized with ethylene oxide (EO).

NovaSure Model 08-09 RF Controllers

NovaSure Model 10 RF Controller

NovaSure RF Controller Description

The NovaSure RF controller is a constant power output generator with a nominal maximum power delivery capability of 180 watts. The controller automatically calculates the power output based on the uterine cavity length (sound measurement minus the length of the endocervical canal) and width measurements that the user key-enters into the controller. Monitoring tissue impedance during the ablation process automatically controls the depth of endo-myometrial ablation. The NovaSure procedure self-terminates once endometrial vaporization and superficial myometrial desiccation have reached 50 ohms of impedance at the tissue-electrode interface, or when the treatment timer reaches two minutes. Integral to the controller is the cavity integrity assessment system (CIA) which is designed to determine whether there is a defect or perforation in the wall of the uterus. After the disposable device is placed into the uterine cavity, CO_2 is delivered through the central lumen of the disposable device into the cavity, via the vacuum feedback tubing, at a safe flow rate and pressure. If the CO_2 pressure in the cavity is maintained for a short period of time, indicating that the uterine cavity is intact, then the CIA will allow the NovaSure RF controller to be enabled and proceed with the treatment phase. A vacuum pump contained within the NovaSure RF controller creates and maintains a vacuum in the uterine cavity throughout the endometrial ablation procedure. Once the vacuum is stabilized, the vacuum level is monitored throughout the remainder of the ablation process.

NovaSure Suction Line Desiccant Description

The NovaSure suction line desiccant is a non-sterile, single-patient use component that the user attaches in-line with the suction tubing, prior to connecting the disposable device to the NovaSure RF controller. The desiccant absorbs the moisture removed from the uterine cavity via the suction tubing during the ablation procedure.

NovaSure Foot Switch Description

The NovaSure foot switch is a pneumatic switch that connects to the NovaSure RF controller front panel. It is used to activate the NovaSure RF controller and does not contain any electrical components.

NovaSure CO_2 Canister Description

The NovaSure CO_2 canister is a 16-gram CO_2 (USP) canister. It is attached to the regulator located on the back panel of the NovaSure RF controller prior to applying line voltage to the NovaSure RF controller. The CO_2 is used by the cavity integrity assessment system to pressurize the uterine cavity.

NovaSure AC Power Cord Description

The NovaSure AC power cord, a medical grade cord, connects the NovaSure RF controller to the appropriate line voltage. The receptacle for the power cord, the power input module, is located on the back panel of the NovaSure RF controller.

INDICATIONS

The NovaSure system is intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

CONTRAINDICATIONS

The NovaSure impedance controlled endometrial ablation system is contraindicated for use in:

- a patient who is pregnant or who wants to become pregnant in the future. **Pregnancies following ablation can be dangerous for both mother and fetus.**
- a patient with known or suspected endometrial carcinoma (uterine cancer) or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- a patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy) or pathologic condition (e.g., long-term medical therapy) that could lead to weakening of the myometrium.
- a patient with active genital or urinary tract infection at the time of the procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis or cystitis).
- a patient with an intrauterine device (IUD) currently in place. Presence of an IUD in the uterine cavity can interfere with a NovaSure procedure.
- a patient with a uterine cavity length less than 4 cm. The minimum length of the electrode array is 4 cm. Treatment of a uterine cavity with a length less than 4 cm will result in thermal injury to the endocervical canal.
- a patient with a uterine cavity width less than 2.5 cm, as determined by the WIDTH dial of the disposable device following device deployment.
- a patient with active pelvic inflammatory disease.

WARNINGS

FAILURE TO FOLLOW ANY INSTRUCTIONS OR FAILURE TO HEED ANY WARNINGS OR CAUTIONS COULD RESULT IN SERIOUS PATIENT INJURY.

THE NOVASURE DISPOSABLE DEVICE MUST BE USED ONLY IN CONJUNCTION WITH THE NOVASURE RF CONTROLLER.

THE NOVASURE PROCEDURE IS INTENDED TO BE PERFORMED ONLY ONCE DURING A SINGLE OPERATIVE VISIT. THERMAL INJURY TO THE BOWEL MAY OCCUR WHEN MULTIPLE NOVASURE THERAPY CYCLES ARE PERFORMED DURING THE SAME OPERATIVE VISIT.

Uterine Perforation

- Use caution not to perforate the uterine wall when sounding, dilating or inserting the disposable device.
- If the disposable device is difficult to insert into the cervical canal, use clinical judgment to determine whether or not further dilation is required.
- The NovaSure system performs a cavity integrity assessment (CIA) to evaluate the integrity of the uterine cavity and sounds an alarm warning of a possible perforation prior to treatment (Step 2.36). **(Although designed to detect a perforation of the uterine wall, it is an indicator only and it might not detect all perforations under all possible circumstances. Clinical judgment must always be used.)**
- **If a uterine perforation is suspected, the procedure should be terminated immediately.**

- **If the cavity integrity assessment fails after reasonable attempts to implement the troubleshooting procedures (step 2.36), abort the procedure.**
- For patients in whom the procedure was aborted due to a suspected uterine wall perforation, a work-up for perforation should be considered prior to discharge.

General

- Endometrial ablation using the NovaSure system is not a sterilization procedure. Therefore, the patient should be advised of appropriate birth control methods.
- Endometrial ablation does not eliminate the potential for endometrial hyperplasia or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- Endometrial ablation is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following the procedure. Pregnancy following ablation may be dangerous for both mother and fetus.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation are at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post procedure.
- A health hazard may exist in the case where the NovaSure procedures is performed in the presence of a thermally and electrically conductive metal micro-insert that is improperly positioned (e.g., perforating the fallopian tube or the myometrium). If this occurs, heat can be drawn away from the intended treatment area toward other tissue and/or organs in contact with the conductive object, which may be sufficient to cause localized burns. As a result, correct placement of the metal micro-insert must be confirmed prior to performing the NovaSure procedure.

Technical

- Do not use the sterile, single-patient use disposable device if the packaging appears to be damaged or there is evidence of tampering.
- The disposable device is for single-patient use only. Do not reuse or re-sterilize the disposable device. The risk of reusing the disposable device includes but is not limited to the following:
  - ineffective procedure
  - infection (major)
  - electric shock
  - transmission of communicable disease
  - cervical laceration
  - uterine perforation
- If any hysteroscopy procedure is performed with hypotonic solution immediately prior to NovaSure treatment, then the uterine cavity must be flushed with normal saline prior to treatment with the NovaSure system. The presence of hypotonic fluid may reduce the efficiency of the NovaSure system.
- Plugging the disposable device into the controller starts CO_2 flow to purge any air out of the disposable device and tubing. This purging operation takes approximately 10 seconds and **must be performed with the disposable device external to the patient to eliminate the risk of air or gas embolism**. The NovaSure RF controller CAVITY ASSESSMENT LED flashes red (Model 08-09 RFCs) or a purging device screen appears (Model 10 RFC) and an audible pulsed tone sounds throughout the purge procedure. When the tone and the LED/screen message stops it is safe to insert the disposable device.
- For patients with cardiac pacemakers or other active implants, a possible hazard exists due to interference with the action of the pacemaker that may occur and may damage the pacemaker. Consult the pacemaker manufacturer for further information when use of the NovaSure system is planned in patients with cardiac pacemakers.
- Care should be taken to ensure the patient does not contact metal parts which are earthed or which have an appreciable capacitance to earth.
- **Danger: explosion hazard.** Do not use in the presence of a flammable anesthetic mixture. Do not use in the presence of flammable gases or liquids.
- Failure of the NovaSure RF controller could result in an unintended increase in output power.

PRECAUTIONS

- It has been reported in the literature that patients with a severely anteverted, retroflexed or laterally displaced uterus are at greater risk of uterine wall perforation during any intrauterine manipulation.
- A false passage can occur during any procedure in which the uterus is instrumented, especially in cases of severe anteverted retroflexed or a laterally displaced uterus. Use caution to ensure that the device is properly positioned in the uterine cavity.
- The NovaSure system consists of the following components:
  - single-patient use NovaSure disposable device with connecting cord
  - NovaSure RF controller
  - NovaSure CO_2 canister
  - NovaSure desiccant
  - NovaSure foot switch
  - power cord

  To ensure proper operation, never use other components with the NovaSure system. Inspect the components regularly for damage, and do not use them if damage is apparent. The use of any cables or accessories other than those specified in these instructions may result in increased emissions or decreased immunity of the RF controller.
- The RF controller must be installed and put into service according to the guidance provided in these instructions to ensure its electromagnetic compatibility. Refer to the electromagnetic emissions and immunity tables in the Specifications section.
- The RF controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the RF controller should be observed to verify normal operation in the configuration in which it will be used.

- Portable and mobile RF communications equipment can affect the RF controller. Refer to the electromagnetic immunity tables in the Specifications section for recommended separation distances.
- Patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have a progestin included in their medication regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of the NovaSure system has not been fully evaluated in patients:
  - with a uterine sound measurement greater than 10 cm;
  - with submucosal fibroids that distort the uterine cavity;
  - with bicornuate, septate or sub-septateuteri;
  - with medical (e.g., GnRH agonist) or surgical pretreatment;
  - who have undergone a previous endometrial ablation including the NovaSure endometrial ablation procedure; or,
  - who are post-menopausal.
- Do not attempt to repair the controller if problems are suspected. Call Hologic Technical Support or a Hologic sales representative for instructions.
- Cables to the disposable device should be positioned such that contact with patient or other leads is avoided.
- The user should inspect the disposable device for damage prior to use.
- The suction line desiccant is non-sterile, and the packaging should not be placed in the sterile field.
- **If the ARRAY POSITION LED light is illuminated on Models 08-09, or an Array Position message is displayed on the Model 10 screen, see the Troubleshooting section under "ARRAY POSITION ALARM"**
- Do not use the NovaSure suction line desiccant if desiccant material is pink in color.
- The disposable device must be external to (outside of) the patient before connecting the cord to the appropriate port on the front panel of the controller (step 2.15).
- The carbon dioxide canister contains gas under high pressure. In the event of a breached CO_2 canister or line, allow the canister to exhaust completely, and allow the canister and/or lines to equilibrate to room temperature prior to handling.
- CO_2 continuously flows from the time that the disposable device is plugged into the controller until the CIA portion of the procedure is complete. To minimize the duration of CO_2 flow and potential risk of embolism, perform the seating procedure immediately after inserting the disposable device and proceed directly from the seating procedure to the CIA.
- Electrically conductive objects (e.g., monitoring electrodes from other devices) that are in direct contact with the electrode array of the disposable device or in close proximity to the electrode array may draw current away from the array. This may result in localized burns to the patient or physician or in distortion of the electrical field of the array, which would change the therapeutic effect (under-treatment or over-treatment). It may also result in distortion of the current in the conductive object, e.g., monitors may display false readings.
- Grounding reliability is only achieved when equipment is connected to a receptacle marked "hospital grade".
- To avoid risk to patient and operators, do not use this equipment in the presence of intentional magnetic sources, intentional ultrasound sources, or intentional heat sources.
- The cervical collar must be fully retracted to its proximal position in order to minimize the potential for damage to the sheath when closing the array.
- The plastic tubing in the NovaSure Disposable Device contains di-(2-ethylhexyl) phthalate; DEHP. In accordance with European Commission Directive 67/548/EEC, it is noted here that DEHP may impair fertility; it also may cause harm to the unborn child. The NovaSure device is contraindicated for use in pregnant women or women that want to become pregnant in the future. Pregnancies following ablation can be dangerous for both mother and fetus. Sound medical judgment should be used.

NovaSure 3-Year Clinical Data

Adverse Events

The NovaSure system was evaluated in a randomized, prospective, multi-center clinical study of 265 patients with abnormal uterine bleeding comparing the NovaSure system to a control arm of wire loop resection of the endometrium followed by rollerball ablation.

Table 1A. Intra-Operative Adverse Events

Adverse Event	NovaSure n=175 (%)	Loop Resection Plus Rollerball n=90 (%)
Bradycardia	1 (0.6%)	0
Uterine perforation	0	3 (3.3%)
Cervical tear	0	2 (2.2%)
Cervical stenosis	0	1 (1.1%)
TOTAL	**1 (0.6%)**	**6 (6.7%)**

Table 1B. Post-Operative Adverse Events < 24 Hours

Adverse Event	NovaSure n=175 (%)	Loop Resection Plus Rollerball n=90 (%)
Pelvic pain/cramping	6 (3.4%)	4 (4.4%)
Nausea and/or vomiting	3 (1.7%)	1 (1.1%)
TOTAL	**9 (5.1%)***	**5 (5.6%)****

* Nine events reported in 6 (3.4%) patients
** Five events reported in 4 (4.4%) patients

Table 1C. Post-Operative Adverse Events > 24 Hours – 2 Weeks		
Adverse Event	**NovaSure n=175 (%)**	**Loop Resection Plus Rollerball n=90 (%)**
Hematometra	1 (0.6%)	0
Urinary tract infection	1 (0.6%)	1 (1.1%)
Vaginal infection	1 (0.6%)	0
Endometritis	0	2 (2.2%)
Pelvic inflammatory disease	0	1 (1.1%)
Hemorrhage	0	1 (1.1%)
Pelvic pain/cramping	1 (0.6%)	1 (1.1%)
Nausea and/or vomiting	1 (0.6%)	1 (1.1%)
TOTAL	**5 (2.9%)***	**7 (7.8%)****

* Five events reported in 4 (2.3%) patients
** Seven events reported in 6 (6.7%) patients

Table 1D. Post-Operative Adverse Events > 2 Weeks – 1 Year		
Adverse Event	**NovaSure n=175(%)**	**Loop Resection Plus Rollerball n=90 (%)**
Hysterectomy	3 (1.7%)	2 (2.2%)
Hematometra	1 (0.6%)	2 (2.2%)
Urinary tract infection	2 (1.1%)	2 (2.2%)
Vaginal infection	5 (2.9%)	2 (2.2%)
Endometritis	2 (1.1%)	1 (1.1%)
Pelvic inflammatory disease	2 (1.1%)	0
Hemorrhage	1 (0.6%)	0
Pelvic pain/cramping	5 (2.9%)	6 (6.7%)
TOTAL	**21 (12.0%)***	**15 (16.17%)****

* 21 events in 19 (10.9%) patients
** 15 events in 15 (16.7%) patients

Anticipated Post-Procedural Complications

For any endometrial ablation procedure, commonly reported post-operative events include the following:

- Cramping/pelvic pain was reported for 3.4% of the NovaSure patients and 4.4% of the wire resection loop plus rollerball-treated patients within 24 hours of the procedure. Postoperative cramping can range from mild to severe. This cramping will typically last a few hours and rarely continues beyond the first day following the procedure.
- Nausea and vomiting were reported for 1.7% of the NovaSure patients and 1.1% of the wire loop resection plus rollerball patients within 24 hours of the procedure. When present, nausea and vomiting typically occur immediately following the procedure, are associated with anesthesia and can be managed with medication.
- Vaginal discharge
- Vaginal bleeding/spotting

Other Adverse Events

As with all endometrial ablation procedures, serious injury or death can occur.

The following adverse events could occur or have been reported in association with the use of the NovaSure system:

- post-ablation tubal sterilization syndrome
- **pregnancy-related complications (NOTE: PREGNANCY FOLLOWING ENDOMETRIAL ABLATION IS VERY DANGEROUS FOR BOTH THE MOTHER AND THE FETUS.)**
- thermal injury to adjacent tissue
- perforation of the uterine wall
- difficulty with defecation or micturition
- uterine necrosis
- air or gas embolism
- infection or sepsis
- complications leading to serious injury or death

Clinical Study

Purpose: Safety and effectiveness of the use of the NovaSure system was compared to wire loop resection of the endometrium followed by rollerball ablation in premenopausal women suffering from menorrhagia secondary to benign causes.

Pretreatment: Patients randomized into the NovaSure arm received no endometrial pretreatment (e.g., hormone, D&C or patient timing). Patients randomized into the control arm received wire loop resection as an endometrial pretreatment.

Study endpoints: The primary effectiveness measure was a validated menstrual diary scoring system developed by Higham (Higham JM, O'Brien PMS, Shaw RW *Br J Obstet Gynaecol* 1990; 97:734-9). Assessment of menstrual blood loss was performed using a pictorial blood loss assessment chart (PBLAC). Patient success was defined as a reduction in menstrual flow at 1 year post-procedure to a diary score of <75. Study success was defined as a statistical difference of less than 20% in patient success rates between the NovaSure impedance controlled endometrial ablation system and wire loop resection plus rollerball ablation. Patients were contacted at two and three years and asked a series of questions regarding their bleeding over the previous 12 months. Each patient's menstrual bleeding status was determined at two and three years using the one-year PBLAC score and bleeding pattern as a reference. Thus, it was possible to directly compare a patient's bleeding pattern or menstrual status at one year to the bleeding pattern at two and three years.

Secondary endpoints included anesthesia regimen, length of procedure and responses from a quality-of-life questionnaire. Safety evaluation was based on the adverse events reported during the study.

Methods: A randomized (2:1), prospective clinical study was conducted at 9 clinical sites and included 265 patients diagnosed with menorrhagia. Menstrual diary scores were collected pre-operatively and monthly for 12 months post-procedure. Patients were treated at any time in their menstrual cycle. None of the patients received hormonal pretreatment to thin the endometrial lining. Control patients received hysteroscopic

wire loop resection of the endometrium as a mechanical means of endometrial pretreatment followed by rollerball ablation. Study subjects were required to meet the following key patient selection criteria:

Inclusion criteria

- Refractory menorrhagia with no definable organic cause (dysfunctional uterine bleeding)
- Ages 25 to 50 years of age
- Uterine sound measurement of 6.0–10.0 cm (external os to internal fundus)
- Minimum PBLAC score of >150 for 3 months prior to study enrollment; or PBLAC score >150 for one month for women who:
  - had at least 3 prior months (documented) failed medical therapy;
  - had a contraindication to medical therapy; or
  - refused medical therapy.

Exclusion criteria

- Presence of bacteremia, sepsis or other active systemic infection
- Active or recurrent chronic pelvic inflammatory disease
- Patient with documented coagulopathies or on anticoagulants
- Symptomatic endometriosis
- Prior uterine surgery (except low segment cesarean section) that interrupts the integrity of the uterine wall e.g., transmural myomectomy or classical cesarean section
- Prior endometrial ablation
- Patient on medications that could thin the myometrial muscle, such as long-term steroid use
- Patient desire to have children or to preserve fertility
- Patient currently on hormonal birth control therapy or unwilling to use a non-hormonal birth control post-ablation
- Abnormal/obstructed cavity as confirmed by hysteroscopy, SIS or HSG. Specifically:
  - septate or bicornuate uterus or other congenital malformation of the uterine cavity
  - pedunculated, submucous leiomyomata or other leiomyomata which distort the cavity; polyps (larger than 2 cm) which are likely to be the cause of the patient's menorrhagia
  - presence of an IUD
- Suspected or confirmed uterine malignancy within the last five years as confirmed by histology
- Endometrial hyperplasia as confirmed by histology
- Unaddressed cervical dysplasia
- Elevated FSH levels consistent with ovarian failure >40 IU/ml
- Pregnancy
- Active sexually transmitted disease

Patient population: A total of 265 patients were enrolled in this study. Patients were between the ages of 25 to 50 with 46% under the age of 40 and 54% 40 years of age or older. There were no differences in demographic or gynecological history parameters between the treatment groups, between the age groupings or among the nine investigational sites.

Table 2. Patient Accountability

Number of Patients	NovaSure	Wire Loop Resection Plus Rollerball
Entered into Study (Intent-to-Treat population)	**175**	**90**
Aborted procedures*[1]	-4	-2
Treated	**171**	**88**
Additional treatment*	-4	-2
Hysterectomy*[2]	-3	-2
Lost to follow-up*	-5	-2
Hodgkin's disease*	-1	0
Pelvic Pain - administered leuprolide*	-1	0
12-Month follow-up data available	**157**	**82**
Additional treatment*	-2	-1
Hysterectomy*[2]	-3	-1
Lost to follow-up*	-2	-5
Missed visit	-1	-1
Declined to participate*	-1	0
Pregnancy*	-1	0
24-Month follow-up data available	**147**	**74**
Additional treatment*	0	-4
Hysterectomy*[2]	-5	-1
Lost to follow-up*	-4	-2
36-Month follow-up	**138**	**67**
Subject lost to follow-up at 24 mos., returned at 36 mos.	+1	+1
36-Month follow-up data available	**139**	**68**

* Discontinued patients
[1] Four NovaSure did not meet protocol Inclusion Criteria; Two Rollerball had uterine perforation
[2] For hysterectomy, see Table 7

Results

Primary effectiveness endpoint: bleeding score

Patient success at 12-months post-procedure is defined as a reduction in diary score from >150 pre-operatively to <75 post-procedure. Amenorrhea is defined as a score of 0. Success at 24 and 36 months, based on telephone questionnaires, is defined as elimination of bleeding or reduction to light or normal flow. Data presented in Table 3 (below) represent the clinical results based on the total number of 265 patients randomized (Intent-to-Treat group (ITT)) for the study. The worst-case scenario is presented whereby each of the discontinued patients

(described in Table 2 for patient accountability) is counted as a "failure" for calculating the values listed in the table.

Table 3. Effectiveness: Success Rates–Intent-To-Treat Patients

	NovaSure (n=175)			Wire Loop Resection Plus Rollerball (n=90)		
Months post ablation	12*	24**	36**	12*	24**	36**
Number of successful patients	136	143	134	67	68	63
Study success rate	77.7%	81.7%	76.6%	74.4%	75.6%	70.0%
# of patients with Amenorrhea	63	64	58	29	26	23
Amenorrhea rate	36.0%	36.6%	33.1%	32.2%	28.9%	25.6%

* Based on diary scores
** Based on telephone questionnaires

Secondary effectiveness endpoint: quality of life

Patient quality of life (QOL) was assessed by administering the quality of life questionnaire (SF-12) and the menstrual impact questionnaire prior to treatment and at 3, 6, 12, 24 and 36 months post-procedure. Table 4 shows the patient responses for both groups pre-operatively, where appropriate, and at 12, 24 and 36 months post-procedure.

Table 4. Effectiveness: Quality of Life (QOL)

	NovaSure	Wire Loop Resection Plus Rollerball
Number of Patients Responding to Quality of Life Questionaire#		
Pre-operatively	175	90
12 Months	154	82
24 Months	143	73
36 Months	139	67
Percent of Patients Satisified Or Very Satisified		
12 Months	92.8%	93.9%
24 Months	93.9%	89.1%
36 Months	96.3%	89.7%
Percent of Patients Who Probably Or Definitely Would Recommend This Procedure		
12 Months	96.7%	95.9%
24 Months	96.6%	94.5%
36 Months	97.8%	92.6%
Percent of Patients with Dysemenorrhea		
Pre-operatively	57.1%	55.6%
12 Months	20.8%&	34.2%*,&
24 Months	20.3%*	30.1%*
36 Months	17.3%*	28.4%*
Percent of Patients with PMS		
Pre-operatively	65.1%	66.7%
12 Months	36.4%*	35.4%*
24 Months	44.0%*	46.6%*
36 Months	34.5%*	41.2%*

Table 4. Effectiveness: Quality of Life (QOL)

	NovaSure	Wire Loop Resection Plus Rollerball
Percent of Patients Reporting Sometimes, Frequently Or Always Have Difficulty Performing Work Or Other Activities Due to Menses		
Pre-operatively	66.3%	65.5%
12 Months	9.9%*	8.6%*
24 Months	14.5%*	15.0%*
36 Months	16.3%*	13.3%*
Percent of Patients Reporting Sometimes, Frequently Or Always Feel Anxious Due to Menses		
Pre-operatively	74.7%	68.9%
12 Months	23.6%*	18.5%*
24 Months	24.2%*	19.2%*
36 Months	18.7%*	19.1%*
Percent of Patients Reporting Sometimes, Frequently Or Always Miss Social Activities Due to Menses		
Pre-operatively	63.3%	62.2%
12 Months	8.5%*	8.6%*
24 Months	9.0%*	11.1%*
36 Months	8.1%*	10.8%*

\# Not all patients completed questionnaire
* Statistically significant difference from pre-operative response (Chi-Square; $p < 0.05$)
& Statistically significant difference between NovaSure and Rollerball Groups (Chi-Square; $p = 0.02$)

Safety endpoint

Adverse event information is described in the "Adverse Events" section of this manual.

Secondary endpoint: procedure time

Procedure time, a secondary endpoint, was determined for each patient by recording the time of device insertion and the time of device removal. The mean procedure time for the NovaSure patients was significantly less than the procedure time for the rollerball group, (4.2 ± 3.5 minutes and 24.2 ± 11.4 minutes, respectively). Mean time for application of RF energy was 84.0 ± 25.0 seconds in a subset of monitored NovaSure patients (Table 5).

Table 5. Operative Procedure Time

Operative Parameters	NovaSure n=175	Wire Loop Resection Plus Rollerball n=90
Number of treated patients*	171	88
Procedure time minutes (± SD) (Device insertion to device removal)	4.2 ± 3.5**	24.2 ± 11.4**
Procedure time in seconds (±SD) (Time of energy delivery)	84.0 ± 25.0	ND#

* See Table 2 for patient accountability
** Statistically significant difference between treatment groups (Student's t-test; $p < 0.05$)
\# Not determined

Secondary endpoint: anesthesia regimen

Anesthesia was left to the discretion of each patient, clinical investigator and attending anesthesiologist. For the NovaSure patients, 27.0% (47/174) had the procedure performed under general anesthesia or epidural and 73.0% (127/174) under local and/or IV sedation. One patient did not have a reported anesthesia regimen in this group. In the rollerball group, 82.2% (74/90) of the patients were treated under general anesthesia or epidural and 17.8% (16/90) under local and/or IV sedation (Table 6).

Table 6. Anesthesia Regimen

	NovaSure n=175*	Wire Loop Resection Plus Rollerball n=90
General or epidural	27.0%	82.2%
Local and/or IV sedation	73.0%	17.8%

* One patient did not have a reported anesthesia regimen.

Clinical observations

Hysterectomy

Fifteen women had a hysterectomy within the three years following the ablation procedure. Table 7 lists the reasons for hysterectomy.

Table 7. Hysterectomy

Reason For Hysterectomy	NovaSure n=175	Wire Loop Resection Plus Rollerball n=90
Adenocarcinoma diagnosed at time of ablation procedure	1	1
Fibroids	2	0
Pelvic abscess	1	1
Endometriosis	3	0
Adenomyosis	4	0
Hematometra	0	1
Menorrhagia	0	1
TOTAL	**11 (6.3%)**	**4 (4.4%)**

7 Hysterectomies were in patients <40 years (7 NovaSure) and 8 hysterectomies were in patients >40 years (4 NovaSure; 4 Rollerball).

Patient Selection

Menorrhagia can be caused by a variety of underlying problems, including, but not limited to; endometrial cancer, myomas, polyps, drugs and dysfunctional uterine bleeding (anovulatory bleeding). Patients always should be screened and evaluated to determine the cause of excessive uterine bleeding before any treatment option is initiated. Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications and hazards prior to the performance of any endometrial ablation procedure.

Patient Counseling

As with any procedure, the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation. Patient's expectations should be set in a way that the patient understands that the aim of the treatment is the reduction in bleeding to normal levels.

The disposable device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following the procedure. Patients of childbearing capacity should be cautioned of potential complications, which may ensue if they should become pregnant. This counseling should include the need for post-procedure contraception where indicated. This procedure is not a sterilization procedure and subsequent pregnancies may be dangerous for the mother and fetus.

Vaginal discharge is typically experienced during the first few weeks following ablation and may last as long as a month. Generally, the discharge is described as bloody during the first few days; serosanguineous by approximately one week; then profuse and watery thereafter. Any unusual or foul-smelling discharge should be reported to the physician immediately. Other common post-procedural complications include cramping/pelvic pain, nausea and vomiting.

Uterine perforation should be considered in the differential diagnosis of any post-operative patient complaining of acute abdominal pain, fever, shortness of breath, dizziness, hypotension or any other symptom that may be associated with uterine perforation with or without damage to the adjacent organs of the abdominal cavity. Patients should be counseled that any such symptoms should be immediately reported to their physician.

Pretreatment Preparation of Patient

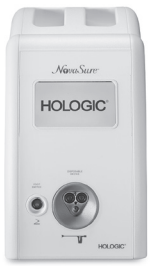
The NovaSure impedance controlled endometrial ablation system successfully treats a uterine cavity over a range of endometrium thickness. The lining of the uterus does not have to be thinned prior to the procedure, and the procedure may be performed during either the proliferative or the secretory phase of the cycle. Although the safety and effectiveness of the NovaSure system has not been fully-evaluated in patients with medical or surgical pretreatment, it has been evaluated in a limited number of patients who had been pretreated with GnRH agonists with no complications or adverse events.

Active bleeding was not found to be a limiting factor when using the NovaSure system. It is recommended that a nonsteroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued postoperatively to reduce intraoperative and postoperative uterine cramping.

NovaSure Impedance Controlled Endometrial Ablation System Instructions For Use

Please read all instructions, cautions and warnings prior to use.

1.0 Set-up



NOVASURE RF CONTROLLER

NOVASURE DISPOSABLE DEVICE WITH CONNECTING CORD, INCLUDING SUCTION LINE DESICCANT

NOVASURE POWER CORD

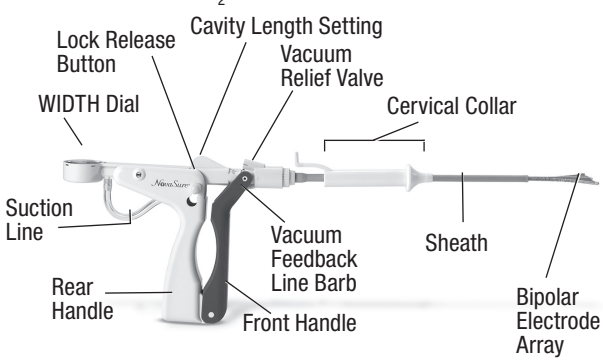
NOVASURE SUCTION LINE

NOVASURE CO_2 CANISTER

NOVASURE FOOT SWITCH

1.1 The following items are required when using the NovaSure system:

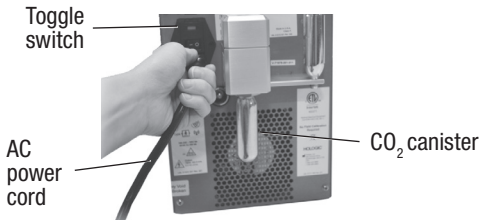
- one sterile, single-patient use NovaSure disposable device with connecting cord
- one NovaSure RF controller
- one NovaSure foot switch
- one NovaSure AC power cord
- one NovaSure non-sterile suction line desiccant assembly
- one NovaSure CO_2 canister.



NOTE: Please have available at least one extra disposable device, desiccant assembly and CO_2 canister.

1.2 Prepare the NovaSure RF controller. Place it on a small table to one side of the patient within visual field of the surgeon. Attach the AC power cord to the controller and plug it into the AC outlet.

1.3 Screw the CO_2 canister into the regulator on the back panel of the controller until tightened.



1.4 Fully rotate the CO_2 regulator knob to the HI position (if equipped).

NOTE: Newer model controllers are not equipped with a knob on the regulator, thus allowing the CO_2 flow to be automatically regulated. If your controller is not equipped with a regulator knob, proceed to step 1.5.

1.5 Press the toggle switch on the back panel of the controller into the "on" position.

1.6 Connect the foot switch to the appropriate port on the front panel of the controller.

NOTE: The first time the Model 10 RFC is turned on, the "Select Your Language" screen will display. The default setting is in English. To select another language, press the button with the name of that language. Save the selection by pressing the flashing green button.

The language selection will be retained. To change the language selection after the initial setup, use the "Settings" screen. Press the name of the language to change the language used on the screen display. To save changes to the settings, press the flashing green button. To cancel a selection, press the Blue "X".

2.0 Procedure

2.1 Prepare the patient for the anesthesia.

2.2 Place patient in dorsal lithotomy position.

2.3 Induce anesthesia according to standard practice.

2.4 Perform bimanual examination. Evaluate for severe anteversion or retroversion.

2.5 Prepare and drape patient similar to prep for D&C.

2.6 Insert a speculum into the vagina.

2.7 Grasp the cervix with a tenaculum.

2.8 Take a sound measurement of the uterus to measure the length from fundus to external cervical os. **The efficacy of the NovaSure system has not been fully evaluated in patients with a uterine sound measurement greater than 10 cm.**

2.9 **Determine the length of the cervical canal and dilate the canal for device insertion.**
NOTE: The diameter of the NovaSure disposable device is a nominal 6 mm.

2.10 Using the uterine sound and cervical canal measurements, consult the cavity length table (below) to obtain the appropriate cavity length settings. On the upper end of the table, dimensions have been adjusted to reflect the disposable device electrode length.
Correct determination of the cavity length is important for safe and effective treatment. Overestimating the cavity length may result in thermal injury to the endocervical canal.

WARNING: Use caution not to perforate the uterine wall when sounding, dilating or inserting the disposable device.

TABLE 8. CAVITY LENGTH

	Uterine Sound (cm)								
Cervix Length (cm)	**10**	**9.5**	**9**	**8.5**	**8**	**7.5**	**7**	**6.5**	**6**
2	6.5*	6.5*	6.5*	6.5	6	5.5	5	4.5	4
2.5	6.5*	6.5*	6.5	6	5.5	5	4.5	4	
3	6.5*	6.5	6	5.5	5	4.5	4		
3.5	6.5	6	5.5	5	4.5	4			
4	6	5.5	5	4.5	4				
4.5	5.5	5	4.5	4					
5	5	4.5	4						
5.5	4.5	4							
6	4								

* The value of 6.5 is not intended to reflect the numerical difference between the sound length and the length of the cervical canal.

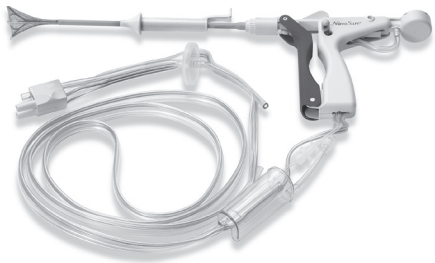
The value 6.5 was entered because it represents the maximum length that the NovaSure array can be extended.

CONTRAINDICATION: Do not treat a patient with a uterine cavity length that is less than 4 cm, as cervical canal damage may occur.

NOTE: Patients with a uterine cavity length greater than 6.0 cm had observed success rates that were lower than overall study success rates.

2.11 Open the sterile NovaSure disposable device package. Place the disposable device with the connecting cord into the sterile field while being careful to keep the non-sterile suction line desiccant box out of the sterile field.

WARNING: Do not use the sterile single-patient use disposable device if the packaging appears to be damaged or there is evidence of tampering.



2.12 Open the non-sterile suction line desiccant box and pouch. Remove the red caps.

CAUTION: The suction line desiccant is non-sterile and the packaging should not be placed in the sterile field.

CAUTION: If the suction line desiccant is pink, then replace it prior to initiating the ablation procedure.

2.13 Connect the desiccant to the barbs on the suction tubing of disposable device. Ensure the barbs are fully inserted into the tubing on the desiccant.

2.14 **CAUTION: Disposable device must be external to (outside of) the patient before performing step 2.15.**

2.15 Connect the disposable device cord to the appropriate port on the front panel of the controller.

WARNING: Plugging the NovaSure disposable device into the NovaSure RF controller starts CO_2 flow to purge any air out of the disposable device and tubing. The purging operation takes approximately 10 seconds and must be performed with the disposable device external to the patient. The NovaSure RF controller CAVITY ASSESSMENT LED flashes red (Model 08-09 RFCs) or a purging device message displays (Model 10 RFC) and an audible pulsed tone sounds throughout the purge procedure. When the tone and the LED/screen message stop, it is safe to insert the NovaSure disposable device.

CAUTION: CO_2 continuously flows from the time that the disposable device is plugged into the controller until the CIA portion of the procedure is complete. To minimize the duration of CO_2 flow and potential risk of embolism, perform the seating procedure immediately after inserting the disposable device and proceed directly from the seating procedure to the CIA.

WARNING: Use caution not to perforate the uterine wall when sounding, dilating or inserting the disposable device.

2.16 Deploy the disposable device outside of the patient and ensure the controller ARRAY POSITION LED is extinguished (Model 08-09 RFCs) or the screen message does not display (Model 10 RFC) when the array is opened. If the LED is not extinguished (Model 08-09 RFCs) or the screen message is still displayed (Model 10 RFC), close and open the disposable device again. If this does not resolve the problem, replace the disposable device.

2.17 Be certain the WIDTH dial reads greater than or equal to 4.0 cm.

NOTE: If the WIDTH dial reads less than 4.0 cm, close the disposable device and repeat step 2.16 above. If the WIDTH dial still reads less than 4.0 cm, open a new disposable device and return the old disposable device to Hologic Technical Support.

2.18 Unlock the disposable device by pressing the lock release button. Close the disposable device by holding the front handle stationary and gently pulling the rear handle backwards until the closed array indicator, located at the hinge of the front and rear handles, reads, “ARRAY CLOSED”. This indicates that the array has been retracted into the sheath and the disposable device is in the closed position.

2.19 Make sure the array is completely enclosed by the external sheath.

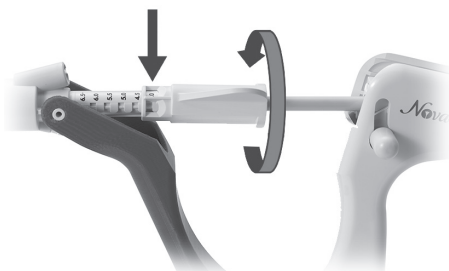
2.20 Check that the WIDTH dial reads approximately 0.5 cm.

2.21 Using the uterine sound measurement and cervical canal measurements, consult the cavity length table (above) to obtain the appropriate cavity length settings as described in step 2.10 above.

CONTRAINDICATION: Do not treat a patient with a uterine cavity length that is less than 4 cm, as cervical canal damage may occur.

2.22 Using the cavity length table in section 2.10, select the value obtained for length into the NovaSure RF controller input screen by depressing the UP/DOWN arrows.

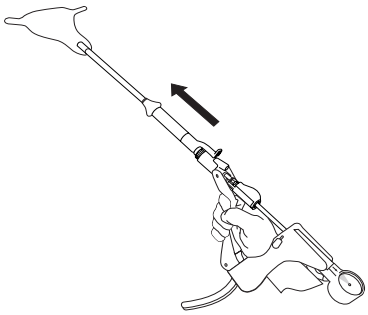
2.23 Adjust and lock the cavity length setting feature on the disposable device to the value obtained above. (See step 2.21.) Ensure that the cervical collar is fully retracted to its proximal position.

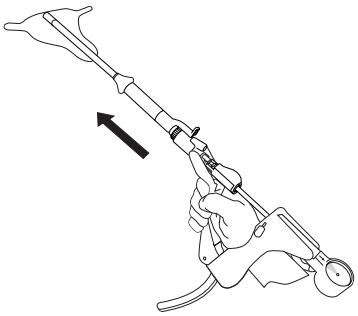


2.24 Confirm that the cervix is dilated to a minimum 6 mm (the nominal diameter of the NovaSure disposable device).

2.25 Maintain a slight traction on the tenaculum to minimize the angle of the uterus.

2.26 Angle the disposable device in-line with the axis of the uterus as the disposable device is inserted transcervically into the uterine cavity. By holding the front handle, advance the disposable device until the distal end of the sheath touches the fundus.

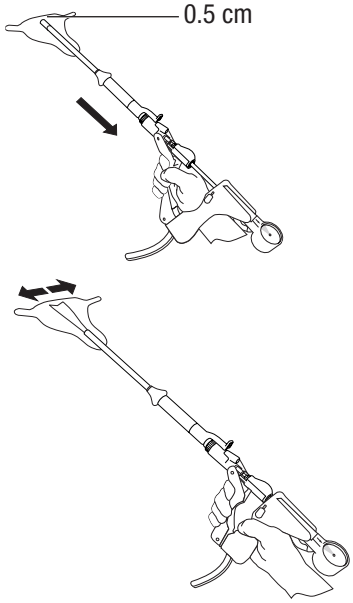




WARNING: If the disposable device is difficult to insert into the cervical canal, use clinical judgment to determine whether or not further dilation is required.

2.27 Withdraw the disposable device approximately 0.5 cm from the fundus. Slowly squeeze the handles (DO NOT LOCK) up to the point of increased resistance.

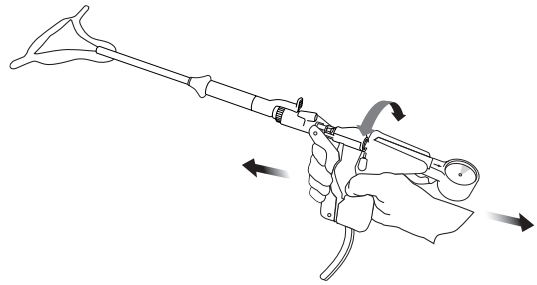
The WIDTH dial should read approximately 0.5 cm. At this point, the external sheath has been retracted.



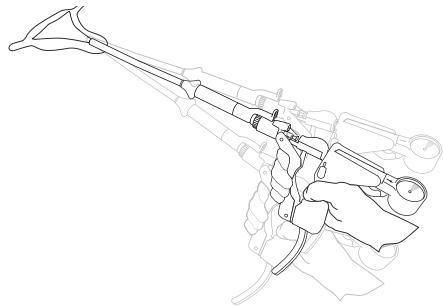
2.28 Continue to slowly squeeze the disposable device handles together while gently moving the disposable device ~0.5 cm to and from the fundus and rotating the handle of the disposable device 45° counterclockwise from the vertical plane and 45° clockwise from the vertical plane until the handles lock.

The WIDTH dial should read greater than 2.5 cm.

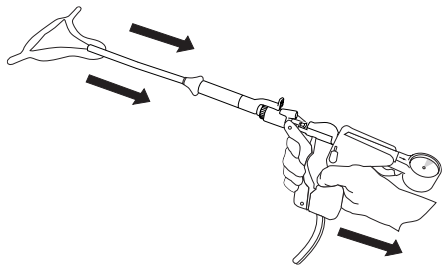
NOTE: Once the disposable device handles are locked, the uterus should move in conjunction with the disposable device.



2.29 Gently move the disposable device using anterior, posterior and lateral movements.

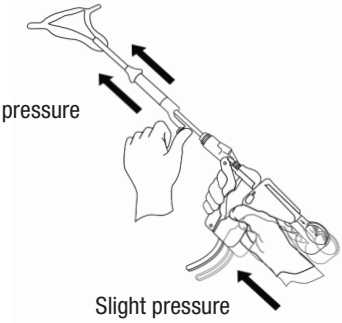


2.30 To complete placement, slightly pull back the disposable device until the WIDTH dial reading reduces by approximately 0.2–0.5 cm.



2.31 Hold the tenaculum, advance the disposable device slowly and gently to the fundus. The WIDTH dial should read greater than or equal to the previous measurement.

2.32 Slide the cervical collar forward using gentle pressure on the tab on the cervical collar, until the cervical collar forms a seal against the external cervical os.



2.33 Read the cornu-to-cornu measurement (2.5 cm minimum) on the WIDTH dial indicator.

CONTRAINDICATION: Do not treat a patient with a uterine cavity width less than 2.5 cm, as determined by the WIDTH dial of the disposable device following device deployment.

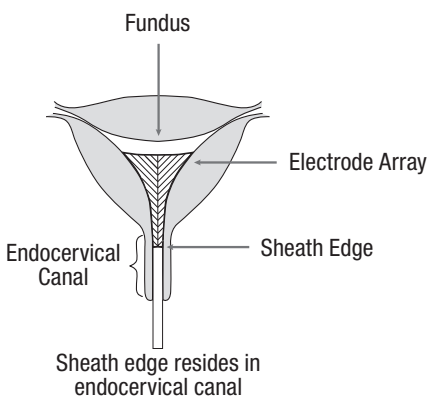
CAUTION: If the ARRAY POSITION notification appears, see the Troubleshooting section under "ARRAY POSITION Alarm."

2.34 Select the value indicated on the WIDTH dial into the NovaSure RF controller input screen by depressing the UP/DOWN arrows.

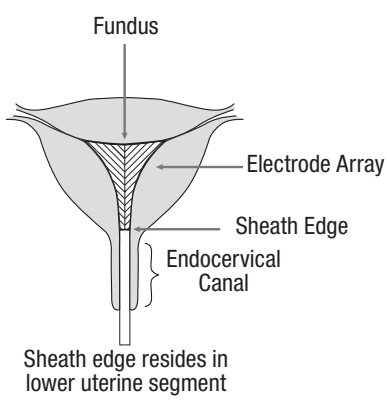
2.35 The system can be operated in either automatic mode or manual mode. In automatic mode the ablation cycle will start automatically upon successful completion of the cavity integrity assessment (CIA). In manual mode the ablation cycle will not start automatically following a successful CIA.

NOTE: Correct placement of the electrode array against the fundus is important to safe and effective treatment. If part of the electrode array or the distal edge of the external sheath is seated in the endocervical canal during treatment, there is an increased risk of endocervical thermal injury.

INCORRECT PLACEMENT



CORRECT PLACEMENT



MODEL 08-09 RF CONTROLLERS

Follow next steps on pages 16 through 19.

MODEL 10 RF CONTROLLER

Follow next steps on pages 20 through 23.

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Additional Troubleshooting 24

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Warranty 29

Technical Support and Product Return Information 29

Symbol Definitions 30

Operating the Model 08-09 RF Controllers

A. Automatic mode

To operate the system in automatic mode, press the ENABLE button prior to beginning the Cavity Integrity Assessment (CIA). Proceed to step 2.36, but do not follow step 2.37 if operating the system in automatic mode.

B. Manual mode

To operate the system in the manual mode, do not press the ENABLE button prior to beginning the Cavity Integrity Assessment (CIA). Follow steps 2.36 and 2.37.

2.36 Begin the CIA procedure by stepping on the foot switch once. The CAVITY ASSESSMENT LED flashes green in conjunction with an audible tone at a rate of once per second when the system is performing a CIA. The duration of the test will range between approximately 7 and 30 seconds. A steady green LED appears when the CIA has passed and the system can deliver RF energy. Power cannot be applied to the disposable device until the CAVITY ASSESSMENT LED is a steady green light.

If the cavity integrity assessment fails, then the CAVITY ASSESSMENT LED on the NovaSure RF controller will flash red, and a rapid audible tone will sound at a rate of four times per second.

If the cavity integrity assessment fails, press the foot switch to stop the sound. Next:

A. If a perforation is suspected, the procedure should be terminated immediately.

B. If the CIA test fails again, check for leaks in the system, and between the cervix and cervical collar. Be sure to check all tubing connections, and ensure that a suction line desiccant has been installed. If the leak appears to be at the cervix and cannot be resolved by using the cervical collar, use another tenaculum to grasp the cervix around the sheath. Repeat the CIA by pressing the foot switch.

NOTE: CO_2 leakage may occur at the external cervical os due to the presence of an over-dilated cervix. Visible bubbles or the "hissing" sound of escaping gas may accompany CO_2 leakage under either of these conditions.

C. If the cavity integrity assessment fails after reasonable attempts to implement the troubleshooting procedures (step 2.36), abort the procedure.

NOTE: Removing the disposable device from the uterine cavity after completing a cavity integrity assessment will require an additional CIA test to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.

2.37 Manual mode only

When operating the system in manual mode, the ablation cycle will not start automatically after the successful completion of the CIA. Once a successful CIA has been completed, press the ENABLE button and depress the foot switch a second time to initiate the ablation cycle.

NOTE: In some Model 09 RF controllers, a vacuum pre-check occurs automatically prior to initiation of the ablation cycle. The VACUUM LED will flash and an audible tone will be heard for up to 10 seconds during the vacuum pre-check.

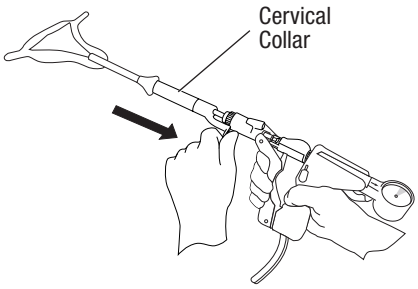
MANUAL MODE

During the ablation cycle, a blue RF ON LED will illuminate. At the completion of the ablation cycle, the RF power delivery (RF ON LED), as well as suction, will switch off automatically. The physician can stop the progress of the procedure at any time by depressing the foot switch.

NOTE: RF power delivery can be stopped at any time by pressing the foot switch

2.38 After automatic termination of the ablation cycle (approximately 90 seconds), fully retract the cervical collar by using the tab on the cervical collar. Fully retract the cervical collar by sliding it to its proximal position.

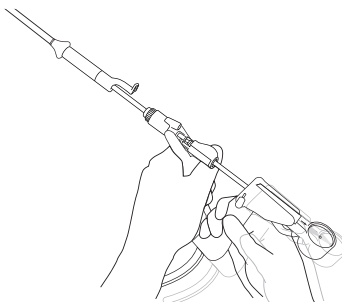
CAUTION: The cervical collar must be fully retracted to its proximal position in order to minimize the potential for damage to the sheath when closing the array.



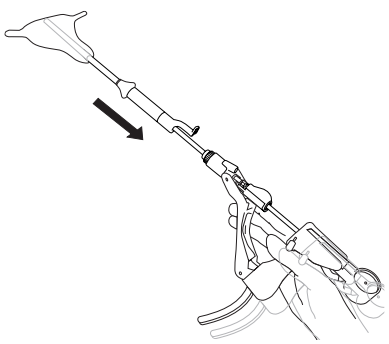
2.39 Unlock the disposable device by pressing the lock release button. Close the disposable device by holding the front handle stationary and gently pulling the rear handle backwards until the closed array indicator, located at the hinge of the front and rear handles, reads "ARRAY CLOSED". This indicates that the array has been retracted into the sheath and the disposable device is in the closed position. (See step 2.18.)

NOTE: If it is difficult to close and remove the disposable device, see the Troubleshooting section, "Difficulty closing and removing the disposable device post-ablation."

CAUTION: To avoid damaging the device, employ gentle technique when retracting the array.



2.40 Withdraw the disposable device from the patient.



2.41 Turn off the NovaSure RF controller. Close the CO_2 regulator.

2.42 Perform postoperative patient care according to standard procedures. The used disposable device must be treated as biohazardous waste and disposed of according to standard practices of the hospital or clinic where the treatment is performed.

2.43 Discharge the patient from the hospital or office as indicated by the managing physician.

Periodic Maintenance and Service

There is no service manual for the NovaSure RF controller since there are no field serviceable components within the unit.

WARNING: No modification of this equipment is allowed.

Periodic maintenance

The RF controller has been designed and tested to meet IEC 60601-1 and other safety standards. Maintenance is not required as the system performs self-checks when power is turned on. To clean the controller refer to the "Cleaning and Sanitizing" section.

RF power output test

The NovaSure RF controller Model 08-09 integrates automatic power output testing into a power on self test (POST). During the POST the controller's power output (Pc) is delivered into a shunt resistor (Rs) located inside the controller. Pc is targeted to be 180 watts and Rs is nominally 25 ohms. During the POST, no power is delivered to the disposable device connector at the front of the controller.

NOTE: If a NovaSure disposable device is connected at the time the controller is powered up, the POST will not be performed and the controller will return to normal operation. If a device is connected during the POST sequence, the POST will terminate and the controller will return to normal operation.

The following procedure is used to execute the POST and display the actual value of Pc and Rs determined:

1. With the switch on the power input module in the off position, check to make sure a disposable device is not connected to the RF controller.
2. Depress and hold the length UP and length DOWN arrows simultaneously, then toggle the power switch at the power input module while continuing to depress the arrows. This step initiates the POST, which proceeds automatically.
3. Upon the completion of the POST (approximately 5 seconds), the RF controller will generate one audible tone, and then display the actual value of Pc for two seconds on the power set LED.
4. After two seconds elapse, the power set LED will change to display the actual value of Rs for two seconds.
5. The power set LED will then change to 00, and the RF controller will return to normal operation without further input from the user.

The acceptable limits on Pc = 180 W ± 10%. If Pc is not within specification, a system fault will occur. The actual value of Rs is for reference only.

NOTE: If a system fault occurs during the POST, toggle off the power at the power input module and repeat the POST. If a system fault occurs a second time, remove the RF controller from service and contact Hologic customer service.

CAUTION: Do not attempt to repair the controller if problems are suspected. Follow the troubleshooting guide in this manual. If problems persist, call Hologic Technical Support for instructions.

Sterile NovaSure disposable device: No maintenance is necessary. Single-patient use only. Do not reuse or re-sterilize the NovaSure disposable device.

NovaSure RF Controller LED Descriptions

The following is a description of the alert LEDs on the NovaSure RF controller.

CAVITY ASSESSMENT LED: illuminates in four modes:

1. Flashes red in conjunction with an audible tone at a rate of once per second for the first 10 seconds when the system is purging air out of the disposable device. After 10 seconds, the LED and audible tone will cease, although CO_2 will continue to flow out of the vacuum feedback line.
2. Flashes green in conjunction with an audible tone at a rate of once per second when the system is performing a cavity integrity assessment.
3. Steady green light appears when the cavity integrity assessment has passed and the system can deliver RF energy. Power cannot be applied to the disposable device until the CAVITY ASSESSMENT LED is a steady green.
4. Steady red lights and an audible tone at a rate of four times per second occur when the cavity integrity assessment has failed. The CIA test may be tried again.

ENABLE LED: illuminates amber when the user presses the ENABLE button. Acts as a safety so that the NovaSure disposable device will not accidentally activate when the foot switch is touched. The ENABLE LED will not illuminate when the ARRAY POSITION LED is on.

RF ON LED: illuminates blue when the ablation is proceeding (the foot switch has been depressed to activate the NovaSure RF controller with the NovaSure disposable device array in place in the uterus).

PROCEDURE COMPLETE LED: illuminates when the tissue impedance reaches 50 ohms and the ablation procedure runs a minimum of 30 seconds.

ARRAY POSITION LED: illuminates red when one pole of the electrode array may be in contact with another. This LED should be illuminated when the array is not fully deployed. The ENABLE LED cannot be toggled on, nor can power be delivered to the array when the ARRAY POSITION LED is illuminated.

VACUUM LED: illuminates in two conditions:

1. Flashes red accompanied by an audible tone while the system is stabilizing the vacuum level for up to 10 seconds before energy delivery commences (only for Model 09 controllers with a vacuum pre-check function).
2. Illuminates red when the vacuum relief valve is stuck in the closed position, when a blockage is detected in the disposable device or the connection tubing or when the system has a leak. Such a situation might be created by:

- an over-dilated cervix with poor contact between the cervical collar and the external os;
- a poor attachment of the desiccant tube to the suction tubing;
- an obstruction in the disposable device tubing; or
- an obstruction in the disposable device.

SYSTEM FAULT LED: illuminates red if the system faults or if there is a self-diagnostic check failure with the system clock or power delivery. If this event occurs, terminate the procedure immediately and contact an authorized Hologic service representative for instructions.

Troubleshooting Most Common Alarms

CAVITY ASSESSMENT LED illuminated red

If the CAVITY ASSESSMENT LED is steady red, the cavity integrity assessment has failed. If the cavity integrity assessment fails, then the CAVITY ASSESSMENT LED on the NovaSure RF controller will flash red, and a rapid audible tone will sound at a rate of four times per second. The CIA test may be tried again.

If a perforation is suspected, the procedure should be terminated immediately.

If the cavity integrity assessment fails, press the foot switch to stop the sound. The cause of the cavity integrity assessment failure is the inability to pressurize the cavity. It may be caused by:

1. Device leak: ensure that the suction line desiccant filter has been installed. Check all tubing connections to ensure that they are tightly connected.
2. Leak at the external os of the cervix: Look for visible bubbles or a "hissing" sound at the external os of the cervix.
   Use the tab on the cervical collar to advance the cervical collar towards the external os of the cervix to ensure there is a tight seal. Test again. If the test fails again, use a second tenaculum to grasp the cervix around the sheath of the NovaSure disposable device. Test again.
3. Uterine perforation: **If a uterine perforation is suspected, the procedure should be terminated immediately.**

NOTE: CO_2 leakage may occur at the external cervical os due to the presence of an over-dilated cervix. Visible bubbles or the "hissing" sound of escaping gas may accompany CO_2 leakage under either of these conditions.

If the cavity integrity assessment fails after reasonable attempts to implement the troubleshooting procedures (step 2.36), abort the procedure.

NOTE: Removing the disposable device from the uterine cavity after completing a cavity integrity assessment will require an additional CIA test to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.

VACUUM LED illuminated

The VACUUM LED illuminates when the vacuum level is outside its specified range. This can occur as a result of one or more of the following:

- an over-dilated cervix;
- poor contact between the cervical collar and the external cervical os;
- the vacuum relief valve is in the closed position;
- an obstruction in the disposable device filter(s) (two) or desiccant; or
- an obstruction within the disposable device.

To eliminate this condition, perform the following:

- Gently press a 2–3.5 mm uterine dilator or sound inside the vacuum relief valve.
- Check the cervical collar position, and reposition it if necessary. Use the tab on the cervical collar to advance the cervical collar towards the external os of the cervix to ensure there is a tight seal. Verify that air is not being drawn through the cervix by a loose fit between the cervical collar and the entrance to the cervical canal. If air is being drawn in through the cervical canal, try to reposition the cervical collar and disposable device shaft to prevent air ingress.
- Ensure the suction canister on the disposable device is vertical and the device tubing is not draped over the patient's leg.
- Check all tubing connections to ensure that they are tightly connected. Check the push-on tubing connectors at the desiccant tube. Replace the dessicant if it is pink. Ensure that the filter located near the disposable connection on the vacuum feedback line is tightened.
- Reattempt ablation.

If the VACUUM LED illuminates again:

- Disconnect the disposable device from the RF controller.
- Remove the disposable device from the patient, then;
- Exchange the disposable device with a new disposable device.
- Reattempt the ablation with the new device.

If a vacuum alarm occurs with the new device, abort the procedure:

NOTE: Removing the disposable device from the uterine cavity after completing a cavity integrity assessment will require an additional CIA test to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.

CO_2 canister low or empty

The NovaSure RF controller will generate an audible tone at a rate of four times per second during this alarm condition. LEDs that were illuminated prior to the alarm will remain in the same state during the low CO_2 event. Pressing the foot switch will not turn off the audible alarm.

1. Replace the CO_2 canister to stop the audible tone.

NOTE: It is not necessary to remove the disposable device from the patient prior to replacing the canister.

2. Continue with the procedure.

ARRAY POSITION LED illuminated

1. Gently move the proximal end of the disposable device and observe if the ARRAY POSITION LED extinguishes. If it does not, proceed with the following:
2. Attempt gentle reseating of the NovaSure disposable device:
   A. Partially retract the array into the sheath by releasing the disposable device handle lock release button;
   B. Pull the disposable device back slightly from fundus;
   C. Slowly redeploy the disposable device array while gently rocking the disposable device back and forth and locking the disposable device handles; and
   D. Reseat the disposable device against fundus using the seating procedure described in steps 2.26 through 2.33.
3. If the uterus is retroverted, take special care to avoid perforation. Apply gentle caudad traction to the cervix with the tenaculum, and elevate the disposable device handle upward toward the ceiling (in-line with the axis of the uterus) while performing the seating procedure.
4. If the ARRAY POSITION LED is still illuminated, fully retract the disposable device array and remove the disposable device from the patient.
5. Deploy the disposable device outside the patient's body; ensure the electrode array is undamaged and that the ARRAY POSITION LED extinguishes.
6. Attempt reinsertion, redeployment and reseating of the disposable device using the seating procedure described in section 2.0.
7. If the ARRAY POSITION LED remains illuminated, replace with a new disposable device.
8. If the ARRAY POSITION LED remains illuminated with a new disposable device, terminate the procedure.

Please turn to page 24 for the remainder of the Instructions for Use.

Operating the Model 10 RF Controller

A. Automatic mode

To operate the Model 10 RFC in Automatic Mode, press the "Switch Mode" button when it appears at the bottom of the screen. Proceed to step 2.36, but do not follow step 2.37 if operating the system in automatic mode.

B. Manual mode

NOTE: Manual Mode is the default system operation.

To operate the system in manual mode, do not press the "Switch Mode" button prior to beginning the cavity integrity assessment (CIA). Follow steps 2.36 and 2.37.

2.36 Begin the CIA procedure by stepping on the foot switch once. "Cavity Assessment in Progress" will display on the screen while five dots light off and on sequentially. The duration of the test will range between approximately 7 and 30 seconds. A "Cavity Assessment Complete" screen displays when the CIA has passed and the system can deliver RF energy. Power cannot be applied to the disposable device until the CIA Complete screen displays.

If the cavity integrity assessment fails, a screen will display "Cavity Assessment Failure" with troubleshooting steps.

A. If a perforation is suspected, the procedure should be terminated immediately.

B. If the CIA test fails again, check for leaks in the system, and between the cervix and cervical collar. Be sure to check all tubing connections, and ensure that a suction line desiccant has been installed. If the leak appears to be at the cervix and cannot be resolved by using the cervical collar, use another tenaculum to grasp the cervix around the sheath. Repeat the CIA test by pressing the foot switch.

NOTE: CO_2 leakage may occur at the external cervical os due to the presence of an over-dilated cervix. Visible bubbles or the "hissing" sound of escaping gas may accompany CO_2 leakage under either of these conditions.

C. If the cavity integrity assessment fails after reasonable attempts to implement the troubleshooting procedures (step 2.36), abort the procedure.

NOTE: Removing the disposable device from the uterine cavity after completing a cavity integrity assessment will require an additional CIA test to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.

2.37 **Manual Mode Only**

When operating the system in manual mode, the ablation cycle will not start automatically after the successfully completion of the cavity integrity assessment (CIA). Once a successful CIA has been completed, press the ENABLE button and depress the foot switch a second time to initiate the ablation cycle.

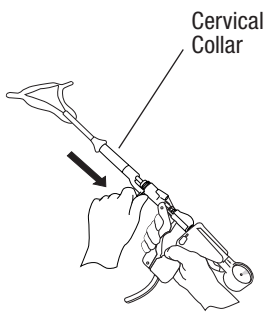
NOTE: In all Model 10 RF controllers, a vacuum pre-check occurs automatically prior to initiation of the ablation cycle. A "Vacuum Check in Progress" screen will appear and an audible tone will be heard for up to 10 seconds during the vacuum pre-check.

During the ablation cycle, an "RF ON" screen with a timer will appear to track the duration of the ablation.

NOTE: RF power delivery can be stopped at any time by pressing the foot switch.

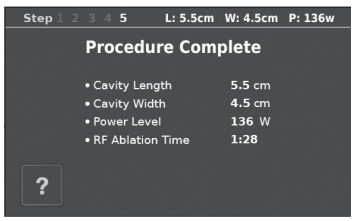
2.38 After automatic termination of the ablation cycle (approximately 90 seconds), fully retract the cervical collar to its proximal position by using the tab on the cervical collar.

CAUTION: The cervical collar must be fully retracted to its proximal position in order to minimize the potential for damage to the sheath when closing the array.



At the completion of the ablation cycle, a “Procedure Complete” screen will appear with a summary of the procedure. The “Procedure Complete” screen will capture the following information for each procedure:

- Cavity Length
- Cavity Width
- Power Level
- RF Ablation Time

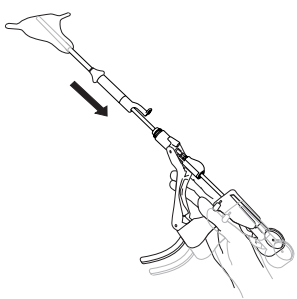

Step 1 2 3 4 5
L: 5.5cm W: 4.5cm P: 136w
Procedure Complete
• Cavity Length 5.5 cm
• Cavity Width 4.5 cm
• Power Level 136 W
• RF Ablation Time 1:28
?

2.39 Unlock the disposable device by pressing the lock release button. Close the disposable device by holding the front handle stationary and gently pulling the rear handle backwards until the closed array indicator, located at the hinge of the front and rear handles, reads “ARRAY CLOSED”. This indicates that the array has been retracted into the sheath and the disposable device is in the closed position.

NOTE: If it is difficult to close and remove the disposable device, see the Troubleshooting section, “Difficulty closing and removing the disposable device post-ablation”.

CAUTION: To avoid damaging the device, employ gentle technique when retracting the array.

2.40 Withdraw the disposable device from the patient.



2.41 TURN OFF THE NOVASURE RF CONTROLLER.

2.42 Perform postoperative patient care according to standard procedures. The used disposable device must be treated as biohazardous waste and disposed of according to standard practices of the hospital or clinic where the treatment is performed.

2.43 Discharge the patient from the hospital or office as indicated by the managing physician.

Periodic Maintenance and Service

There is no service manual for the NovaSure RF Controller since there are no field serviceable components within the unit.

WARNING: No modification of this equipment is allowed.

Periodic maintenance

The RF controller has been designed and tested to meet IEC 60601-1 and other safety standards. Maintenance is not required as the system performs self-checks when power is turned on.To clean the controller refer to the “Cleaning and Sanitizing” section.

RF power output test

The NovaSure RF controller Model 10 integrates automatic power output testing in a power on self test (POST). During the POST the controller’s power output (Pc) is delivered into a shunt resistor (Rs) located inside the controller. Pc is targeted to be 180 watts and Rs is nominally 25 ohms. During the POST, no power is delivered to the disposable device connector at the front of the controller.

The NovaSure RF controller Model 10 performs POST automatically upon power up. To access POST information, go to Settings and scroll to System Information. Press the “View Info.” button.

NOTE: If a system fault occurs during the POST, toggle off the power at the power input module and repeat the POST. If a system fault occurs a second time, remove the RF controller from service and contact Hologic customer service.

CAUTION: Do not attempt to repair the controller if problems are suspected. Follow the troubleshooting guide in this manual. If problems persist, call Hologic Technical Support for instructions.

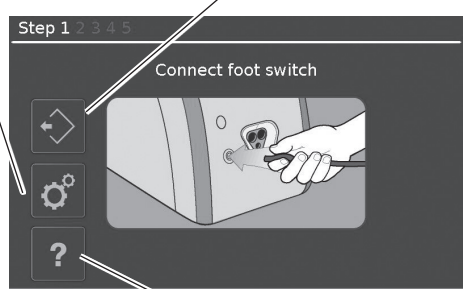
Sterile NovaSure disposable device: No maintenance is necessary. Single-patient use only. Do not reuse or re-sterilize the NovaSure disposable device.

NovaSure Model 10 RF Controller Screen Icons

The following is a description of the icons on the NovaSure Model 10 RF controller screen.

Settings Icon:
Press this button to display the setting options for Language, Brightness, and Volume.

Last Procedure Icon:
Press this button to display the “Procedure Complete” Screen and review the summary from the last procedure.



Help Icon:
Press this button to display more information regarding the current step of the procedure. This icon will display an abridged version of the IFU language.

NOTE: When the "Last Procedure" Icon is pressed, only the previous procedure will be displayed. Information for procedures prior to the most recent procedure will not be available.

NOTE: In the "Settings" screen, press the "-" or "+" buttons to adjust the volume and brightness.

NOTE: The first time the Model 10 RFC is turned on, the "Select Your Language" screen will display. The default setting is in English. To select another language, press the button with the name of that language. Save the selection by pressing the flashing green button. The language selection will be retained. To change the language selection after the initial setup, use the "Setting" screen. Press the name of the language to change the language used on the screen display. To save changes to the settings, press the flashing green button. To cancel a selection, press the blue "X".

Troubleshooting Most Common Alarms

CAVITY ASSESSMENT ALARM

If the cavity integrity assessment fails, a screen will display "Cavity Assessment Failure" with an abridged version of the troubleshooting tips below. The cause of the cavity integrity assessment (CIA) failure is the inability to pressurize the cavity. It may be caused by:

1. Device leak: Ensure that the suction line desiccant filter has been installed. Check all tubing connections to ensure that they are tightly connected.
2. Leak at the external os of the cervix: Look for visible bubbles or a "hissing" sound at the external os of the cervix.

   Use the tab on the cervical collar to advance the cervical collar towards the external os of the cervix to ensure there is a tight seal. Perform the CIA test again. If the CIA test fails again, use a second tenaculum to grasp the cervix around the sheath of the NovaSure disposable device. Perform the CIA test again.
3. Uterine perforation: **If a perforation is suspected, the procedure should be terminated immediately.**

NOTE: CO_2 leakage may occur at the external cervical os due to the presence of an over-dilated cervix. Visible bubbles or the "hissing" sound of escaping gas may accompany CO_2 leakage under either of these conditions.

NOTE: When following the troubleshooting steps on the Model 10 RFC, press the "?" button on the screen and use the scroll buttons on the right for more information. To get back to the main screen from the additional troubleshooting tips, press the "X" in the top right corner of the screen.

If the cavity integrity assessment fails after reasonable attempts to implement the troubleshooting procedure (step 2.36), abort the procedure.

VACUUM ALARM

The Vacuum alarm occurs when the vacuum level is outside its specified range. This can occur as a result of one or more of the following:

- An over-dilated cervix;
- Poor contact between the cervical collar and the external cervical os;
- The vacuum relief valve is in the closed position;
- An obstruction in the disposable device filter(s) (two) or desiccant; or
- An obstruction within the disposable device.

If the Vacuum check fails, a screen will display "Vacuum Failure" with an abridged version of the following troubleshooting tips:

- Gently press a 2-3.5 mm uterine dilator or sound inside the vacuum relief valve
- Check the cervical collar position, and reposition if necessary. Use the tab on the cervical collar to advance the cervical collar towards the external os of the cervix to ensure there is a tight seal. Verify that air is not being drawn through the cervix by a loose fit between the cervical collar and the entrance to the cervical canal. If air is being drawn in through the cervical canal, try to reposition the cervical collar and disposable device shaft to prevent air ingress.
- Ensure the suction canister on the disposable device is vertical and the device tubing is not draped over the patient's leg.
- Check all tubing connections to ensure that they are tightly connected. Check the push-on tubing connectors at the desiccant tube. Replace the desiccant if it is pink. Ensure that the filter located near the disposable connection on the vacuum feedback line is tightened.
- Reattempt ablation.

If the "Vacuum Failure" screen displays again:

- Disconnect the disposable device from the RF controller.
- Remove the disposable device and replace with a new disposable device.
- Reattempt the ablation with the new device.

NOTE: When following the troubleshooting steps on the Model 10 RFC, press the "?" button on the screen and use the scroll buttons on the right for more information. To get back to the main screen from the additional troubleshooting tips, press the "X" in the top right corner of the screen.

If the vacuum alarm occurs with the new device, abort the procedure.

NOTE: Removing the disposable device from the uterine cavity after completing a cavity integrity assesment will require an additional CIA test to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.

CO_2 canister low or empty

A screen will display "Replace CO_2" with an image of the back of the controller. An audible tone will be generated at a rate of 1 time per second. Alarm messages that were present prior to the alarm will remain in the same state during the replace CO_2 event. Pressing the foot switch will not turn off the audible alarm.

1. Replace the CO_2 canister to stop the audible tone.

NOTE: It is not necessary to remove the disposable device from the patient prior to replacing the canister.

2. Continue with the procedure.

ARRAY POSITION Alarm

The Array Position message displays when the array is not open fully. The controller cannot perform ablation when Array Position message displays. If the ARRAY POSITION alarm occurs, a screen will display "Check Array" with an abridged version of the following troubleshooting tips:

1. Gently move the proximal end of the disposable device and observe if the Array Position message no longer displays. If it still displays, proceed with the following:
2. Attempt gentle reseating of the NovaSure disposable device:
   A. Partially retract the array into the sheath by releasing the disposable device handle lock release button;
   B. Pull the disposable device back slightly from the fundus;
   C. Slowly redeploy the disposable device array while gently rocking the disposable device back and forth and locking the disposable device handles; and
   D. Reseat the disposable device against the fundus using the seating procedure described in steps 2.26 through 2.33.
3. If the uterus is retroverted, take special care to avoid perforation. Apply gentle caudad traction to the cervix with the tenaculum, and elevate the disposable device handle upward toward the ceiling (in-line with the axis of the uterus) while performing the seating procedure.
4. If the Array Position message still displays, fully retract the disposable device array and remove the disposable device from the patient.
5. Deploy the disposable device outside the patient's body; ensure the electrode array is undamaged and that the Array Position message no longer displays.
6. Attempt reinsertion, redeployment and reseating of the disposable device using the seating procedure described in section 2.0.
7. If the Array Position message still displays, replace with a new disposable device.
8. If the Array Position message displays with a new disposable device, terminate the procedure.

NOTE: When following the troubleshooting steps on the Model 10 RFC, press the "?" button on the screen and use the scroll buttons on the right for more information. To get back to the main screen from the additional troubleshooting tips, press the "X" in the top right corner of the screen.

Please turn to next page 24 for the remainder of the Instructions for Use.

Additional Troubleshooting

Suspected uterine perforation

Prior to Application of Energy:	During or after Application of Energy:
1. Terminate the procedure	1. Terminate the procedure
2. Assure patient stability	2. Assure patient stability
3. Consider work-up for perforation	3. Rule out visceral injury
4. Reschedule procedure, if appropriate	4. Reschedule procedure, if appropriate

Array does not fully deploy and lock in uterus

1. Partially retract array into sheath (hold the front handle stationary and pull the rear handle back and away from the patient);
2. Reposition the disposable device in the cavity;
3. Redeploy the array in cavity;
4. If the disposable device does not lock, remove it from the uterus;
5. Inspect the disposable device for damage;
6. Attempt to open the disposable device and lock it outside the patient;
7. If damaged, the replace disposable device;
8. If the disposable device is not damaged, reinsert it into the patient's uterine cavity and attempt deployment; and
9. If unable to deploy the disposable device to a minimum 2.5 cm cornu-to-cornu distance, terminate the procedure.
10. Consider uterine perforation as a possible cause for not deploying.

Difficulty closing and removing the disposable device post-ablation

Confirm that the lock release button is depressed:

- If so, gradually withdraw the disposable device from the patient.
- If not, press the lock release button and reattempt to close the disposable device. If it is still difficult to close, gradually withdraw the disposable device from the patient.

ENABLE LED will not illuminate (Model 08-09 RFCs only)

Be sure:

1. The ENABLE button is firmly depressed;
2. The NovaSure RF controller is plugged in;
3. The toggle switch at the back of the controller is on; and
4. The ARRAY POSITION LED is not illuminated.

PROCEDURE COMPLETE LED not illuminated (Model 08-09 RFCs) or "Procedure Complete" Screen does not appear (Model 10 RFC) at the end of a procedure

1. If power has not been applied for at least 30 seconds, the LED will not illuminate (Model 08-09 RFCs) or the "Procedure Complete" Screen will not appear (Model 10 RFC). Remove the NovaSure disposable device from the uterus after fully retracting the disposable device array into the sheath:
   A. Release the disposable device lock release button;
   B. Hold the disposable device front handle steady; and
   C. Pull the disposable device rear handle backward.
2. Inspect the disposable device for any damage. Fully deploy the electrode array outside the patient, demonstrating that the ARRAY POSITION LED does not illuminate (Model 08-09 RFCs) or that the message does not display (Model 10 RFCs).
3. If the disposable device is not damaged and the ARRAY POSITION LED extinguishes (Model 08-09 RFCs) or the message screen does not appear (Model 10 RFC), reinsert, redeploy and reattempt treatment.
4. If the problem persists, replace the disposable device with a new disposable device.
5. Reattempt the procedure. If the problem persists, terminate the procedure.

RF ON LED will not illuminate (Model 08-09 RFCs) or the "RF ON" screen will not appear (Model 10 RFC)

1. If the NovaSure RF controller is plugged in, switched on, the ENABLE button has been pressed and no power is delivered from the controller when the foot switch is depressed, check the foot switch connection. Also make sure the CAVITY ASSESSMENT has passed.
2. If the problem persists, terminate the procedure.

UP/DOWN values will not appear when pressing the appropriate buttons

Make sure that the disposable device is connected to the controller. The values will not appear unless the disposable device is properly connected to the controller.

Replacement Instructions

The NovaSure RF controller uses a pair of fuses that are located on a fuse carrier in the power input module. Type T5AH, 250 V fuses are used. The module can be accessed by using a slotted screwdriver to pop open the fuse carrier door. If required, the fuse carrier may then be removed and the fuses changed. Assembly is the reverse of these steps. Any potentially defective NovaSure product must be returned to Hologic for evaluation. Follow the instructions at the end of this manual in the Service Returns section, for obtaining a returned materials authorization number (RMA #). Do not discard the NovaSure disposable device.

NovaSure disposable device

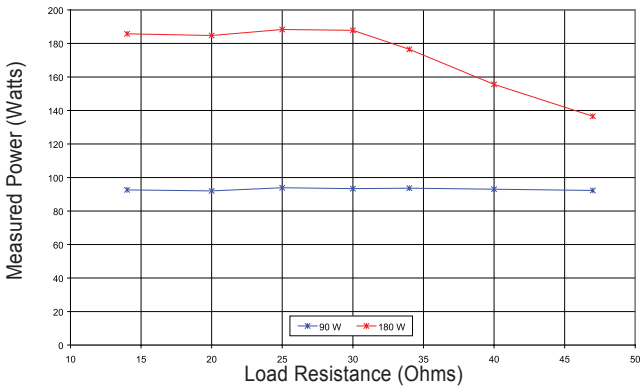
1. The NovaSure disposable device does not contain latex.

2. The NovaSure disposable device is a Class III device by FDA regulation.
3. The NovaSure disposable device is a Class IIB device according to the MDD 93/42/EEC.
4. The NovaSure disposable device tip nominal diameter: 6 mm.
5. The NovaSure disposable device overall dimensions: 19" x 6" x 12" (48.3 cm x 15.2 cm x 5 cm).
6. The NovaSure disposable device has a voltage rating of 153 V.

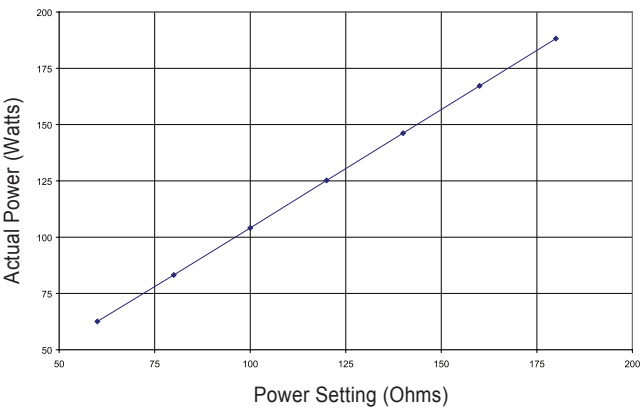
NovaSure RF controller

1. The NovaSure RF controller can be used with outlets providing 100 to 240 VAC and will draw a maximum of 5 Amps.
2. The NovaSure RF controller is a Class I, defibrillator-proof Type BF instrument, according to IEC 60601-1.
3. The NovaSure RF controller is a Class III device by FDA regulation.
4. The NovaSure RF controller is a Class IIB device according to the MDD 93/42/EEC.
5. The RF controller has been tested and found to comply with the limits for medical devices according to IEC 60601-1-2 ED 4.0: 2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
   - Re-orient or relocate the receiving device
   - Increase the separation between equipment
   - Connect the equipment into an outlet on a circuit different from that to which the other device(s) is/are connected.
   - Contact Hologic Technical Support (or the manufacturer of the other equipment) for assistance.
6. The controller meets the requirements of IEC 60601-1/UL 60601-1, IEC 60601-2-2 and CSA C22.2 No.601.1.
7. Shipment of the controller should be done only in the original Hologic packaging. Environmental requirements for use, shipping and storage are indicated below.
8. The absolute maximum peak voltage generated by the NovaSure RF controller is 153 volts. Accessories used with the RF controller should have a voltage rating equal to or greater than 153 volts.
9. The absolute maximum peak power generated by the NovaSure RF controller is 216 watts.
10. NovaSure RF controller weight: 24 lbs (11 kg), unpacked.
11. Height: 12.5"; Width: 7.5"; Depth: 14.5" (32 cm x 19 cm x 35.5 cm).
12. The maximum pressure of CO_2 delivered from the NovaSure RF controller and disposable device shall be 90 ± 10 mmHg.The maximum flow rate of CO_2 from the NovaSure RF controller connected to the disposable device shall be 95 ± 15 ml/ min. (The maximum flow rate of CO_2 from the NovaSure RF controller without a NovaSure disposable device attached is 117 ± 13 ml/ min.)
13. The Novasure RF Generator should be used without a neutral electrode.

Power vs. Resistance



Actual Power vs. Power Setting into a 20 Ohm Load



Operating, non-packaged conditions

Altitude	0 to 10,000 ft	(0 to 3,030 m)
Temperature	10° C to 40° C	(50° F to 104° F)
Humidity	15 to 85% RH at 40° C (non-condensing)	

Non-operating, packaged conditions

Altitude	0 to 40,000 ft	(0 to12,120 m)
Temperature	–30° C to 60° C	(–22° F to 140° F)
Humidity	85% RH, 72 hr, at 38° C (non-condensing)	

Essential Performance:

• Air must be purged from the device for 10 seconds prior to insertion in patient.

• The Cavity Integrity Assessment (CIA) must measure a pressure of 50 ± 10 mm of Hg for 3 seconds minimum to pass. Otherwise the CIA will report an error. The RF controller will not enable an ablation to begin until CIA passes.

• RF power: The range of RF power delivery is 55 to 180 (+/-20%) watts.

• Vacuum pressure monitoring: During an ablation the vacuum pressure must be in the range of 0.7 ±0.2 in Hg to 6 ±1.0 in Hg. If the vacuum pressure exceeds this range, the controller will end the ablation.

• Impedance monitoring: The RF Controller will end an ablation when the measured tissue impedance reaches 50 ohms. The controller also will act the same if the impedance is measured as less than 0.5 ohms.

• Two minute timer: After two minutes of RF energy delivery, the controller will end the ablation

• Ten minute timeout: after completing the ablation procedure the controller times out for 10 minutes, during which the controller is incapable of delivering energy.

• DC Short Circuit protection: If the RF controller detects a short circuit (i.e. <13+/-6ohms), the ablation will be ended.

Guidance and manufacturer's declaration – electromagnetic emissions and immunity

The NovaSure RF controller is intended for use in the electromagnetic environment specified below. The customer or user of the NovaSure RF controller should ensure that it is used in such an environment.

Electromagnetic emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The NovaSure RF controller must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The NovaSure RF controller is intended for use in Professional Healthcare Facilities including hospitals and physician's offices. **WARNING: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.**
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

WARNING: In some circumstances, the potential exists for alternate site burns whenever a high-frequency device is used. Skin-to-skin contact should be avoided, for example, by insertion of dry gauze.

WARNING: With any electrosurgical device, the potential for arcing exists, and neuromuscular stimulation may occur.When this device is used properly in the uterus, the risk of muscle stimulation, particularly heart muscle, is remote.

ELECTROMAGNETIC IMMUNITY

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2kV, ±4kV, ±8kV Contact ±2kV, ±4kV, ±8kV, ±15kV Air	±2kV, ±4kV, ±8kV Contact ±2kV, ±4kV, ±8kV,±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrical fast transient/ burst IEC 61000-4-4	±0.5kV, ±1kV, ±2 kV for power supply lines 100kHz repetition frequency	±0.5kV, ±1kV, ± 2kV for power supply lines 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1 kV line(s) to line(s) ±0.5kV, ±1kV, ±2 kV line(s) to earth	±0.5kV, ±1 kV line(s) to line(s) ±0.5kV, ±1kV, ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interuptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % UT ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % U ; 25/30 cycles Single phase: at 0° 0 % UT ; 250 cycles	0 % UT ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % U ; 25/30 cycles Single phase: at 0° 0 % UT ; 250 cycles This condition causes the RF controller to shut down and then return to standby mode.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NovaSure RF controller requires continued operation during power mains interruptions, it is recommended that the NovaSure RF controller be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m 50 Hz	30 A/m 50 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the RF generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	$d=1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.7GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7GHz 80% AM at 1 kHz	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RF generator is used exceeds the applicable RF compliance level above, the RF generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RF generator.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the NovaSure RF controller

The NovaSure RF controller is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NovaSure RF controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NovaSure RF controller as recommended in the following table, according to the maximum output power of the communications device.

Recommended separation distance

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Cleaning and Sanitizing

The use of nonflammable agents for cleaning and sanitizing is recommended. Flammable agents or solvents for cleaning or sanitizing should be allowed to evaporate before use of the NovaSure system.

The NovaSure RF controller is not sterile. Cleaning should be done using a mild detergent and water solution to wipe surface areas only. Do not immerse unit in liquid or introduce liquid into the cooling vents or RF cable areas.

The NovaSure disposable device is a sterile disposable device for single-patient use only.

- Do not use if the packaging is opened or damaged.
- Do not reuse or re-sterilize the disposable device.

Do not sterilize any component of the NovaSure impedance controlled endometrial ablation system.

Parts List

Ordering information and related parts and accessories

Product Number	Description
RFC2009	NovaSure RF Controller, Model 09
RFC2010	NovaSure RF Controller, Model 10
814002	Power Cord, 115 Volts, North America
814003	Power Cord, 230 Volts, Europe
814004	Power Cord, 220 Volts, United Kingdom/Ireland
814005	Power Cord, Denmark
814009	Power Cord, Italy
814011	Power Cord, Switzerland
814015	Power Cord, Japan
814016	Power Cord, Australia
RFC2000-FS	Foot Switch
815012	CO_2 (USP), Cylinder 5 Pack
NS2013	NovaSure Impedance Controlled Endometrial Ablation Disposable Device Kit
NS2013KIT	NovaSure Kit: 3 NovaSure Impedance Controlled Endometrial Ablation Disposable Devices packaged with 3 SureSound devices
300001	Biohazard Kit

Warranty

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in

a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

Technical Support and Product Return Information

WARNING: Dropping the RF controller voids the warranty and could damage the controller beyond repair. We strongly recommend a stable cart which includes strapping or stabilizing the controller to reduce the risk of being dropped. Please use extra care if transporting the RF controller to an off-site facility. If you have any questions regarding the RF controller, please call 1-800-442-9892 or (508) 263-2900.

Service representatives

Should the NovaSure RF controller become inoperable, contact Hologic Technical Support for instructions and a return materials authorization number (RMA #). Clean and repackage the controller appropriately and return it for repair or servicing to the authorized locations listed below. If the controller is not under warranty, an appropriate handling and repair charge will be established at receipt and examination of the NovaSure RF controller.

For More Information

For Technical Support or reorder information in the United States, please contact:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Phone: 800-442-9892 (toll-free)
www.hologic.com

NOTE: Any disposable device-related incident or problem, which is believed to represent a safety issue, should be reported to Hologic Technical Support.

International customers, contact your distributor or local Hologic Sales Representative:

EC REP

Hologic Ltd.
Heron House Oaks BusinessPark, Crewe Road,
Wythenshawe, Manchester, M23 9HZ, UK
Phone: +44 (0)161 946 2206

Federal law (USA) restricts this device to sale by or on the order of a physician with appropriate training.

Service returns

Read these instructions prior to returning any used/unused potentially defective product to Hologic.

Contact Hologic Technical Support if the NovaSure disposable device or RF controller fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable.

Return RF controllers according to the instructions provided by Technical Support. Be sure to clean the RF controller before returning it and include all accessories in the box with the returned unit.

Return used or opened disposable devices according to the instructions provided with the Hologic-supplied biohazard kit.

Hologic and its distributors and customers in the European Community are required to comply with the Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC). Hologic is dedicated to meeting country specific requirements related to the environmentally sound treatment of its products. Hologic's objective is to reduce the waste resulting from the disposal of its electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE to potential reuse, treatment, recycling or recovery to minimize the amount of hazardous substances entering the environment. Hologic customers in the European Community are responsible for ensuring that medical devices marked with the following symbol, indicating that the WEEE Directive applies, are not placed into a municipal waste system unless authorized to do so by local authorities.

Contact Hologic Technical Support to arrange for proper disposal of the RF controller in accordance with the WEEE Directive.

Symbol Definitions

Alternating current (AC)	
Atmospheric pressure limitation	
Batch code	
Carbon dioxide	
Catalog number	
Category non-AP equipment	
CE marking of conformity with notified body identification number	
Dangerous voltage	
Date of manufacture	
Defibrillator-proof Type BF equipment	
Do not resterilize	
Do not re-use	
Do not stack above “n” high	
Do not use if package is damaged	
Equipotential ground	
European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC	
Foot switch	
Follow instructions for use	
Fragile	
Fuse	
High pressure	HP
Humidity limitation	
Keep dry	
Manufacturer	
No oil	
Not made with natural rubber latex	
Protect from heat	
Radio frequency (RF) energy (non-ionizing radiation)	
Serial number	SN
Sterilized using ethylene oxide	STERILE EO
Sterilized by irradiation	STERILE R
Temperature limitation	
This side up	
Use by	
Contains or presence of phthalate	

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AW-09898-000 Rev. 012